Just Allocation of Health Care Resources

Summary: To articulate and critically evaluate ethical frameworks that can be used to guide decision making about the allocation of scarce health care resources and various mechanisms for allocating scarce resources.

Section: Ethics and Health Policy—Unit on Prioritization

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Background: Health care resources are inherently scarce. Physicians and other providers can do more to improve health than society can—and is willing to—pay for. Not only must health care services compete against other health care services for limited resources but must also compete against other goods and services, the arts, defense, environment, transportation, and housing, for services. While this has always been true, it is becoming increasingly true with advances in medical technologies and increasingly recognized not just by academics and policymakers but also by practitioners and the public. Further, the financial constraints of health care, the need to allocate scarce resources, is an issue confronting all countries, developed and developing, around the world including many wealthy countries with universal coverage of comprehensive benefits.

There have been many different ways of addressing the need to allocate resources. Some have rejected the importance of ethical considerations in this matter, suggesting this is an economic not an ethical problem. Another, and quite common, approach has been denial. Politicians and some health policy makers have denied that there is a need to allocate health care resources. Frequently, it

is argued that if "the fat" were cut, there would be no need for rationing. That is, efficiency would preclude the need for allocating scarce resources. Others have been more forthright and suggested different approaches such as cost-effectiveness analysis. Bioethicists have tried to advance substantive principles for the allocation of scarce resources, such as Daniels' principle of fair equality of opportunity which urges allocating health care resources to enhance people's opportunity to realize their life plans.

What has become clear is that these substantive principles—whether cost-effectiveness analysis or the fair equality of opportunity principle—cannot address the problem because they have deep ethical problems or because of a paucity of data or, most importantly, because they are simply too abstract and insufficiently action guiding for the real allocating decisions; that is they cannot inform policy makers about whether to cover one specific service rather than another service. Consequently, over the last decade or so, researchers have elaborated a variety of procedural approaches to allocating health care resources. Some of these approaches have been to empower physicians or others to make the allocation decisions. Others have defined rigorous procedural steps that must be followed for the fair allocation of health care resources.

Objectives:

- 1) To critically evaluate the ethical justification and appropriateness of proposals for allocating health care resources.
- 2) To critically evaluate the implementation of mechanisms for allocating health care resources.
- 3) To delineate and justify frameworks for the fair allocation of health care resources.

Methodology: The Department began with the conviction that ethics was essential to the allocation of health care resources, that this was not just an economic issue. To develop this case the Department developed and sponsored a conference on ethics and health policy to explore the various connections between ethics and health policy with a focus on the issue of allocating resources.

The Department identified three key allocation decisions in which ethics played a pivotal role, but were not well developed. First, in the late 1990s health plans were attempting to reduced expenditures by providing financial incentives to physicians with reduce services. These financial incentives were mainly different variants of capitation payments. In collaboration with researchers at Harvard Medical School's Center for Ethics in Managed Care, the Department analyzed the ethics of capitation by recognizing that it formed a type of conflict of interest and tried to articulate how the conflict of interest framework helped in

devising ethical forms of capitation. The goal was to articulate safeguards to minimize the effects of this conflict, specifically ways to minimize the likelihood of the conflicts and the harm that might result if they occurred.

Second, due to pressures from expensive new drugs and rising costs of existing new drugs various managed care, health insurance, and pharmacy benefits managements companies were being forced to ration drug benefits. In the heat of rising costs and the need for cost containment, various approaches were being used, apparently without any consideration of the ethical implications. The Department decided to examine systematically from an ethical perspective each of these approaches. The Department delineated critical values that were to be achieved by pharmacy benefits management. It then evaluated how each of the pharmacy benefits management policies, such as tiered co-payments or quarterly caps, incorporated or undermined these values. It then indicated which policies were unethical and among those policies that were not clearly unethical, which values the policies emphasized and which ones they tended to give less emphasis to.

A third issue was more general. If there was not going to be a substantive principle or set of principles for allocating health care resources, then what would constitute ethically justifiable procedures? This required examining the literature on fair procedures and democratic deliberation and adapting the ideas to health care systems. It also involved examining other views advocating procedural approaches to the same issue.

Results: The conference on ethics and health policy was held in October 1999. It served as the basis for a book that explored the various ways in which ethical considerations enter into the development of health care policy and guide the specific policies that result. The conference and the book challenged major bioethicists and health policy makers to engage each other and reflect on the link between ethics and health policy. It showed an intimate link both in the making of health policy as well in specific issues such as adjudicating between populations and individual patients, accountability, and even health services research.

Regarding capitation, it was argued that all compensation systems for physicians entail an inherent conflict of interest, fee for service encourages over use of services, while capitation reimbursement encourages under use. This means that capitation is not inherently unethical, but that efforts must be made to ensure the likelihood of the conflict and the harms that might result were minimized. The research delineated 5 dimensions or characteristics that should be considered in designing an ethical capitation systems. These characteristics include: 1) intensity of the incentives; 2) immediacy of the incentives; 3) targeting of specific services; 4) balance of financial incentives with other incentives; and 5) fairness of the incentives. These characteristics provided a way to delineate more and less ethical capitation policies.

The Department delineated 6 key values for pharmacy benefits management: 1) accepting resource constraints, 2) helping the sick, 3) protecting the worst off, 4) respecting autonomy, 5) sustaining trust, and 6) promoting inclusive decision-making. It then delineated how well of each major method for pharmacy benefits management including formularies, step therapy, prior authorization, capitation for physicians, tiered co-payments, and benefit caps realized these values. It clearly rejected as unethical benefit caps, and suggested that tiered co-payments and formularies could be ethically structured and also suggested how modifications might make them even more ethically acceptable.

In considering procedural approaches to the more general problem of allocating health care resources, the procedures must be compatible with justice. The allocation of health care resources is about the fair distribution of resources. These procedures should fulfill the same ethical requirements as the fair distribution of other resources adapted to the nature of health care system and institutions. In several places, the Department articulated such procedural principles and refined them over time. The latest version delineates 4 overarching ideals:

- 1) Improving health
- 2) Fair sacrifice
- 3) Trust
- 4) Self-determination

These ideals it is argued should be universally endorsed for health care systems. Then 5 procedural principles are delineated to realize these ideals.

- 1) Fair consideration—the interests of each individual needs to be considered in the formulation of policy.
- 2) Openness or publicity—policies should be made available to those affected by them.
- 3) Empowerment—individuals should have the opportunity to participate in the formulation of policies.
- 4) Appeal—individuals should have mechanisms for objecting to policies and their implementation.
- 5) Impartiality—those entrusted with developing and implementing policies should not have a conflict of interest.

Again, these principles should be widely endorsed and compatible with a variety of different ways of allocating resources. In this sense, they make clear that different allocation schemes providing different services to individuals can all be just. The ideals and principles do constrain how decision are made and rule out many of the ways decisions are currently made in health care systems.

This framework of ideals and principles has also provided grounds for criticizing alternative procedural approaches to the allocation of health care

resources, particularly "accountability for reasonableness" as proposed by Daniels and Sabin. In particular, this view is criticized on two grounds by different members of the Department. First, it is criticized as not recognizing the importance of empowerment—of having no mechanism for allowing individual affected by the allocation policies to influence policy formulation, that is for offering too passive a set of procedural principles. It is also criticized for lacking any principle of impartiality. Second, the Daniels and Sabin approach has been criticized as only addressing issues of how to deal with uncertainty about the effects of medical interventions and not how to choose between established effective interventions if one cannot implement all for reasons of limited resources. This is really another form of denial—not taking the need to actually ration care and deny people effective interventions seriously.

Future Directions: One future direction is a comprehensive critique of Daniels' view. Before he left to the University of Toronto, Gopal Sreenivasan started delineating a critique of Daniels' view. This critique noted that Daniels' equal opportunity principle rested on the idea that health care was special; that is, health care should be a matter of justice and distributed according to the principle of fair equality of opportunity because it was special in the way it guaranteed and enhanced individuals' opportunity to realize their life plans. In the last 5 years or so, Daniels has been advocating the importance of social determinants in securing individuals' health. According to the social determinants view, health care is not special in determining health, other factors, income, social inequality, control over one's environment and other undetermined factors are more important than health care in affecting health. On this analysis, health care is not special in guaranteeing or enhancing individuals' opportunities and should not be guaranteed. This work should be published in the near future.

Another direction is for Ezekiel Emanuel to develop his view on vouchers as a way of guaranteeing universal health care coverage that provides a mechanism to control health care costs and provide individuals more choice of health care coverage than the current system. The idea is further develop the claim that the major barrier to universal coverage is political and that any proposal must satisfy both liberal wishes for universal coverage and conservative wishes to empower individuals with their own choices.

A third direction is to work with various health plans to implement the ethical procedural decision-making processes delineated by the Department. This is being planned in conjunction with several different groups—see write up for Ethical Practices in Managed Care.

A fourth direction is to work out the details of the principles for fair allocation developed previously, focusing on the principle of empowerment. Daniels and Sabin are rightly skeptical of having community representatives on decision making bodies because it is difficult or impossible to specify who represents the "community." We will propose a different framework modeled

after the reporting and monitoring procedure of the United Nation system of monitoring a right to health, and after procedures used by the Nation Institute for Clinical Excellence in Britain. The basic idea is to specify how patient advocacy groups should provide input to health policy proposals and how health policy makers have to respond to their concerns before decisions are made and implemented without necessarily having representatives of these groups on decision making bodies.

Publications:

Pearson SD, Sabin JE, Emanuel EJ. Ethical guidelines for physician compensation based on capitation. <u>New England Journal of Medicine</u> 1998;339:689-693.

Burton SL. Why liberals should embrace managed care. <u>Journal of Health</u> Politics Policy and Law 1999;24:911-919.

Titlow K, Emanuel E. Employer decisions and the seeds of backlash. <u>Journal of</u> Health Politics Policy and Law 1999;24:941-947.

Emanuel EJ. Justice and managed care: four principles for the just allocation of health care resources. <u>Hastings Center Report</u> 2000;30(3):8-16.

Burton SL, Randel L, Titlow K, Emanuel EJ. The ethics of pharmaceutical benefit management. Health Affairs 2001;20 (5):150-163.

Emanuel EJ. Hastings Center Report 2002;32:32-34.

Danis M, Clancy C, Churchill LR (eds.). *Ethical Dimensions of Health Policy* (New York: Oxford University Press 2002).

Emanuel EJ. Review of *Setting Limits Fairly*. New England Journal of Medicine 2002;347:953-4.

Lie R. Review of *Setting Limits Fairly*. <u>Journal of Health Politics Policy and Law</u> 2003; (in press).